REMARKS/ARGUMENTS

Applicants wish to thank Examiner Humera N. Sheikh for his considered response and prior art references cited in the Office Action and for withdrawing previous rejections.

Reconsideration of the above-identified patent application is respectfully requested in view of the foregoing amendments and following remarks. Claims 1-3 have been amended, and claims 7-12 have been added. Claims 1-12 remain in the case.

Claims 1-3 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Allegedly the claims contain subject matter which is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Examiner specifically identified "stentless suture" within the claim language as new matter. Accordingly Applicants have replaced "stentless suture" with "suture." The term "suture" is defined in the instant specification (page 6, line 19 - page 7, line 2). Furthermore, the term "suture" is known to those skilled in the relevant art. Applicants respectfully request that the 35 U.S.C. 112, first paragraph rejection be withdrawn.

Claims 1-3 were also rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Again the Examiner specifically identified "stentless suture" within the claim language as indefinite and unclear. Accordingly Applicants have replaced "stentless suture" with "suture."

Claims 1-6 were rejected under 35 U.S.C. §103(a) as being unpatentable over Narayanan (US Patent No. 6,919,100) in view of Shaw et al. (US Patent No. 6,918,869). The Examiner stated that Narayanan teaches a dip coating process where layers of aqueous latex are added to medical devices to [passively] eliminate the biological organism's reaction to said medical devices

(Abstract). Narayanan also teaches adding at least one drug, agent and/or compound, in therapeutic doses, to the aqueous latex polymeric emulsion for the treatment of a predetermined condition (col. 2, lines 56-62).

Dissimilarly, Applicants' invention utilizes PTFE, a porous material allowing absorption of a biological agent. The biological agent more effectively and actively reduces undesirable intimal hyperplasia, smooth muscle cell proliferation. Sustained dosing and release rate of the biological agent are controlled by Applicants via the thickness and density of PTFE (page 8, lines 11-19).

Shaw et al., cited by the Examiner, teach the use of PTFE strips or "graft coverings" that are used to hold the biologically active material in a matrix and prevent abrasion of the device against the vessel wall and scar tissue (col. 13, lines 57-67). Within the same citation, Shaw et al. specifies that the "graft" may be sutures or strips attached or interwoven into the ends of a stent, which holds the biologically active material. Transitively Shaw teaches that a "graft covering" not the "graft" itself is benefited by fabrication from PTFE. But Narayanan teaches applying a coating to medical devices, not permeating the pores of the medical device's material, an intrinsic property of PTFE. As such, the Examiner's observation that one of ordinary skill could incorporate the PTFE of Shaw et al. within the suture/grafts of Narayanan is not disclosed or suggested. Applicants respectfully request that the 35 U.S.C. 103(a) rejection be withdrawn.

Claims 1-6 were also rejected under 35 U.S.C. §103(a) as being unpatentable over Mollison et al. in view of Shaw et al.

The Examiner cited Mollison et al. who teach a medical device comprising a supporting structure having a coating on the surface thereof, the coating containing a therapeutic substance, such as a drug. Supporting structures for the medical devices include arterio-venous grafts and bypass grafts (see Abstract; and col. 4, lines 57-65).

Additionally, Mollison et al. teach a method of treating a variety of disease states, including restenosis, post-transplant tissue rejection, immune and autoimmune dysfunction, fungal growth and cancer (col. 4, lines 53-56).

Additionally, the Examiner stated that, according to Mollison et al., the coating can comprise any polymeric material. The purpose of the coating is to serve as a controlled release vehicle for the therapeutic agent or as a reservoir for a therapeutic agent to be delivered at the site of a lesion (col. 12, lines 2-7).

Mollison et al. describe "a medical device comprising a supporting structure having a coating on the surface thereof…" (Abstract). Furthermore, Mollison et al. reiterate their invention scope: "In addition to stents, other devices that can be used to introduce the drugs of this invention to the vasculature include, but are not limited to grafts, catheters, and balloons" (col. 11, lines 64-66). Applicants' invention, however, does not comprise a supporting structure as taught by Mollison et al. nor does Mollison et al. provide a practical example of a coating material, such as PTFE, capable of serving as a controlled release vehicle for the therapeutic agent or as a reservoir for a therapeutic agent to be delivered at the site of a lesion.

As aforementioned, Shaw et al. teach the use of PTFE strips or "graft coverings" that are used to hold the biologically active material in a matrix and prevent abrasion of the device against the vessel wall and scar tissue (col. 13, lines 57-67). The Examiner's observation that one of ordinary skill could incorporate the PTFE of Shaw et al. within the graft systems of Mollison et al. is neither disclosed nor suggested in the reference. Applicants respectfully request that the 35 U.S.C. §103(a) rejection be withdrawn.

Referring now to "Response to Arguments" section in the Office Action dated June 28, 2007 where the Examiner withdrew the 35 U.S.C. §112, 1st paragraph rejection of claims 1-6 and the U.S.C. §102(e) rejection of claims 1 and 3, again, Applicants thank Examiner Humera N. Sheikh for withdrawing his rejections.

Referring now to "Response to Arguments" section in Office Action where the Examiner maintained the 35 U.S.C. §103(a) rejection of claims 1-6 over Narayanan in view of Shaw et al. The Examiner stated that in his opinion Applicants have not established how PTFE sutures disclosed by the prior art are distinct from the PTFE suture claimed in the instant invention. Applicants respectively request that the Examiner reconsider his rejection based on the argument set forth above that the instant invention describes sutures constructed of PTFE and permeating the pores of the PTFE with releasable biological agents, not merely applying a coating to a medical device. Furthermore Narayanan explicitly and implicitly teaches coating medical devices, notably omitting references to sutures or similar articles. Shaw et al. mention PTFE strips for covering sutures but do not describe sutures fabricated from PTFE. The instant invention has a clear and useful advantage over combinations of the referenced art by controllably releasing biological agents as recited in the claims. Duration and rate of release are controlled by the density and thickness of the PTFE material.

Referring now to "Response to Arguments" section in Office Action where Examiner maintained his 35 U.S.C. §103(a) rejection of claims 1-6 over Mollison et al. in view of Shaw et al. The Examiner stated that in his opinion Applicants have not demonstrated a sufficient showing of any unexpected or superior results attributed by the 'stentless suture' of the invention. The Examiner further stated that Applicants have not disclosed how their sutures would distinguish over the sutures taught in the art. Applicants respectively request that the Examiner reconsider his objection based on the argument set forth above that the invention describes sutures constructed of PTFE and permeating the pores of the PTFE with releasable biological agents, not merely applying a coating to a medical device. Furthermore Mollison et al. explicitly and implicitly teach coating medical devices, notably omitting references to sutures or similar articles. Shaw et al. mention PTFE strips for covering sutures, but do not describe sutures fabricated from PTFE. The instant invention has a clear and useful advantage over combinations of the referenced art by controllably releasing biological agents. Duration and rate of release are controlled by the density and thickness of the PTFE material.

For these reasons Applicants request withdrawal of all rejections, allowance of claims 1-16, and passing of the application to issue.

Respectfully submitted,
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